Exhibit 300: Capital Asset Summary

Part I: Summary Information And Justification (All Capital Assets)

Section A: Overview & Summary Information

Date Investment First Submitted: 2009-06-30
Date of Last Change to Activities: 2012-02-24
Investment Auto Submission Date: 2012-02-24
Date of Last Investment Detail Update: 2012-02-24
Date of Last Exhibit 300A Update: 2012-02-24
Date of Last Revision: 2012-02-24

Agency: 009 - Department of Health and Human Services **Bureau:** 10 - Food and Drug Administration

Investment Part Code: 01

Investment Category: 00 - Agency Investments

1. Name of this Investment: FDA ORA Automated Laboratory Management

2. Unique Investment Identifier (UII): 009-000005318

Section B: Investment Detail

1. **Provide a brief summary of the investment, including a brief description of the related benefit to the mission delivery and management support areas, and the primary beneficiary(ies) of the investment. Include an explanation of any dependencies between this investment and other investments.**

ALM encompasses QMiS, eLEXNET, and LIMS. It provides for ORA wide program quality, sample analysis information sharing across ORA and with external partners, and increased throughput via laboratory automation. ALM aligns directly with Strategic Goal 2, Objective C of the HHS strategic plan: Advance Scientific Knowledge and Innovation; Invest in the regulatory sciences to improve food/medical product safety; and to meet FDA Strategic Goal 4: Improve the Quality/Safety of Manufactured Products/Supply Chain. QMiS supports program quality across FDA. This includes the review, continuous improvement, and auditing of work product from the regulatory work flows of ORA. QMiS also directly supports the accreditation of the 16 ORA labs. eLEXNET allows the exchange of lab analysis data between over 100 public health labs at the Federal, state, and local levels including an interface with DHS' National Bio-surveillance Integration System. It is the system for the Food Emergency Response Network and is thus an integral piece in protecting against bioterrorism. LIMS is an envisioned ORA wide COTS solution for automating laboratory work that is currently done manually. This will significantly increase throughput and is expected to at least double the current capacity of ORA laboratories. This is a key component to supporting the FDA Science Strategic Plan. Primary beneficiaries of ALM are quality managers, organizations participating in eLEXNET, and the personnel in the ORA labs. This extends to the public as ALM enables protecting and promoting the public health. ALM will

result in reduced response times in health emergencies due to increased laboratory throughput and leveraging external partners and in increased quality for repeatability of results and directly supports the ORA mission of protecting and promoting the public health. ALM has significant dependencies on both MARCS and RBIS for work flow and reporting. ALM forms a comprehensive solution for sample analysis that incorporates quality, internal laboratories, and external partners. It is a proven success in leveraging external partners through cooperative agreements and a useful and reliable IT system. ALM has a planned end date of 9/30/2014. FDA is exploring the possibility of combining ALM, MARCS, and RBIS into one investment since together they support ORA regulatory work flows. This analysis will be completed in FY12. ALM is now being reported as ending pending the results of this analysis.

2. **How does this investment close in part or in whole any identified performance gap in support of the mission delivery and management support areas? Include an assessment of the program impact if this investment isn't fully funded.**

ORA is a geographically dispersed organization with many processes having grown up organically over decades. QMiS addresses these differences by using a systematic approach towards quality and standardization. This involves a cultural change within the organization and will take time to be accepted. eLEXNET provides a proven method of interfacing with external partners, particularly DHS. In the case of a bioterrorism emergency, cooperation between Federal agencies and private partners will be paramount. eLEXNET provides a robust, fully redundant, and reliable system to do this. ORA has seen a steep growth in the demand for sample analysis while many essential processes are not yet automated. All of the 16 ORA laboratories use manual paper based processes. LIMS is being implemented to change this to automate the laboratories from top to bottom. This will increase accuracy, throughput, and staff efficiency. The demand for sample analysis work from the ORA laboratories is only expected to grow. Without an automated system, it will be virtually impossible for laboratories using manual processes to meet the needs of the organization. eLEXNET was the first system at FDA to take a SOA approach coupled with a BPMS. Both LIMS and MARCS are being designed to extend this approach. This provides ORA with an architecture that supports integration and information interchange from the ground up. SOA provides the technical backbone for this approach. The BPMS standardizes the approach to defining, describing, mapping, and implementing work flows and enables Federal business personnel to build and modify work flows as graphical and English language tools do not require a technical background. This produces a more accurate and useful final product work flow and cuts modification time. ALM fills the current performance gap by providing improved quality, external partner communications, and laboratory automation. This improves repeatability, communication, addresses chain of custody legal needs, increases laboratory throughput, and reduces response time to public health emergencies. Not fully funding ALM will delay these benefits and could result in ORA laboratories not being able to process samples as needed by the organization.

3. **Provide a list of this investment's accomplishments in the prior year (PY), including projects or useful components/project segments completed, new functionality added, or operational efficiency achieved.**

PY accomplishments: eLEXNET: continued implementation of extranet based/externally hosted service sharing real-time food safety information system for proactive collaboration with federal/state/local government labs. 24x7system availability with help desk support

O&M plus security, troubleshooting/problem resolution incorporating National Biosurveillance Integration System and Electronic Laboratory Exchange Network (NEIS) –interface with DHS' National Bio-surveillance Integration System Standardized data web-based interfaces Design/Pilot - common login QMIS: Deployment of first release. Available for use by all ORA federal personnel. This supports document control and ???. LIMS: Acquisition of services and COTS software.

4. **Provide a list of planned accomplishments for current year (CY) and budget year (BY).**

ALM CY planned accomplishments: QMIS: Plan and deploy interface from QMIS to Recall Enterprise System for recalled human food products Initiate TURBO Enterprise Inspection Report (EIR) Integrate with MARCS Integrate with ORA Reporting, Analysis and Decision Support System (ORADSS) for Imports Expanded on-site user training Increase user licenses as systems are rolled out to ensure maximum availability and use eLEXNET: Standardize data web-based interfaces – including system oversight, upgrades, security, troubleshooting and resolution Implement common login for easier system use Help desk support optimization Create standardized data interface for participating labs Enable common login for easier system use by FERN members LIMS: Analysis and review of architecture to support 14 geographically dispersed sites from a centralized data center while supporting very large data sets within each particular laboratory. This will take into account the particular needs of laboratory instrumentation versus business equipment. Conduct two Pilots for microbiology. Implementation of LIMS in a first ORA laboratory. ALM BY planned accomplishments: QMIS: Continued integration with MARCS Transfer Operational Qualification (TOQ) testing eLEXNET: Expanded data fields Facilitate outreach activities Integration with MARCS Laboratory Management Information System (LIMS): Implementation of LIMS in three ORA laboratories. Inclusion of two more disciplines such as chemistry or devices into LIMS. Full build out of hardware infrastructure.

5. **Provide the date of the Charter establishing the required Integrated Program Team (IPT) for this investment. An IPT must always include, but is not limited to: a qualified fully-dedicated IT program manager, a contract specialist, an information technology specialist, a security specialist and a business process owner before OMB will approve this program investment budget. IT Program Manager, Business Process Owner and Contract Specialist must be Government Employees.**

2009-07-21

Section C: Summary of Funding (Budget Authority for Capital Assets)

1.

Table I.C.1 Summary of Funding

	PY-1 & Prior	PY 2011	CY 2012	BY 2013
Planning Costs:	$0.6	$0.5	$0.5	$0.2
DME (Excluding Planning) Costs:	$16.5	$12.9	$11.7	$12.0
DME (Including Planning) Govt. FTEs:	$0.7	$0.3	$0.3	$0.3
Sub-Total DME (Including Govt. FTE):	$17.8	$13.7	$12.5	$12.5
O & M Costs:	$14.3	$2.4	$3.2	$3.3
O & M Govt. FTEs:	$0.6	$0.1	$0.1	$0.1
Sub-Total O & M Costs (Including Govt. FTE):	$14.9	$2.5	$3.3	$3.4
Total Cost (Including Govt. FTE):	$32.7	$16.2	$15.8	$15.9
Total Govt. FTE costs:	$1.3	$0.4	$0.4	$0.4
# of FTE rep by costs:	11	4	4	4
Total change from prior year final President's Budget ($)		$2.1	$-0.1	
Total change from prior year final President's Budget (%)		15.16%	-0.43%	

2. If the funding levels have changed from the FY 2012 President's Budget request for PY or CY, briefly explain those changes:

The value used for calculating Government FTEs has changed according to FDA guidance. This has resulted in a slight reduction in the funding levels.

Section D: Acquisition/Contract Strategy (All Capital Assets)

Table I.D.1 Contracts and Acquisition Strategy

Contract Type	EVM Required	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	IDV Agency ID	Solicitation ID	Ultimate Contract Value ($M)	Type	PBSA ?	Effective Date	Actual or Expected End Date
Awarded	7524	HHSF223200950013C									
Awarded	7524	HHSF223200950015I									
Awarded	7524	HHSF223201000047I									
Awarded	7524	HHSF223201110027I									
Awarded	7524	HHSF223200850026C									
Awarded	7524	IND11PX19157									

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:
Contracts included in item 1 were executed prior to the implementation of EVM requirements and thus do not include a clause requiring EVM reporting. Contract number 7 does not include EVM language since the dollar value is underneath any EVM reporting threshold.

Exhibit 300B: Performance Measurement Report

Section A: General Information

Date of Last Change to Activities: 2012-02-24

Section B: Project Execution Data

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
287489	FDA ORA ALM Laboratory Information Management System (LIMS) Proof of Concept	LIMS Proof of Concept: This focuses on the development of an electronic means to replace a paper based process. The form 431 is used throughout the ORA laboratories to record the actions of analysts and the results of operations. This requires an analyst to write down actions and results. This information must then later be manually entered into the legacy MARCS Field Accomplishments and Compliance Tracking System (FACTS). This is a time consuming and error prone process. The goal of this proof of concept is to demonstrate the effectiveness of making this one form electronic as a precursor to a full blown LIMS.			
287491	FDA ORA ALM Laboratory Information Management System (LIMS) Program Management Technical Coordination (PMTC)	This project provides program level activities to support work across all of LIMS. LIMS is divided into a set of activities that may be concurrent or sequential			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		and that require a high degree of coordination to ensure the optimum design and ultimate implementation across all 16 FDA ORA labs. ORA has 14 static laboratory locations in buildings and two mobile laboratory units that can be driven to a particular location. PMTC is essential to the management of the LIMS program that will include an comprehensive assessment phase of the current status of the lab systems' environment, IT interface needs, the creation of at least two Test Labs, determining the design of optimum IT systems, and the implementation in each of the 16 FDA/ORA labs. PMTC also includes handling IT security considerations and configuration management across LIMS.			
287492	FDA ORA ALM Laboratory Information Management System (LIMS) Laboratory Assessment and Pilots	This includes a Lab Assessment and the necessary activities to assess, plan for, and design the implementations for a LIMS for all 16 ORA laboratories including the coordination of activities with OIM and ORA. This also includes pilots of LIMS in four of the ORA laboratories at the Northeast Regional Laboratory (NRL), the Denver, Colorado (DEN) laboratory, the Pacific Regional Laboratory (PRL), and the Southeast Regional Laboratory. The Lab Assessment includes reviews and analyses to produce a workable design for the ORA laboratories. This includes functionalities across and within			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		all ORA labs; workflow processing analysis; review of requirements for the pilots; data center versus local hosting; validation of network design; security requirements; business process models (“To-Be” state), gap analysis; a preliminary LIMS design; expected baseline performances and recommended levels of capacity; and analysis of future LIMS-MARCS-RBIS Integration. Lab Assessment outcomes include: Recommendations regarding network and firewall configurations; server architecture to support data, application, and web tiers; meeting security requirements, management approaches; and other outputs such as refined LIMS requirements, management plan; business process models; work flow process documentation; and, a preliminary design for LIMS. Lab Pilots 1-4: Provide a LIMS solution at each laboratory. This is focused on microbiology and will build on the Lab Assessment results. These pilots will allow ORA to prove out the recommendations adopted from the Lab Assessment and lay the groundwork for the expansion of LIMS to all of the 16 ORA labs. The LIMS solution will require configuration to accommodate possible different business processes and lab instruments particular to individual FDA laboratories and will require integration with other FDA			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		systems. Activities in the Pilots include: Review proposed Pilot design; develop Pilot(s) to help prove technical concepts; Integrate the LIMS with commercial off-the-shelf (COTS) products with FDA enterprise systems to form a LIMS solution. Initiating LIMS configuration; Utilizing custom development; Conducting system testing (functional testing, unit testing, system testing, integration testing, and user-acceptance testing); Procuring software licenses Providing LIMS Pilots with integration to lab instruments; Deploying planning for the Pilots; Developing Pilot Documentation; and, Implementing the Pilots.			
287496	FDA ORA ALM Electronic Laboratory Exchange Network (eLEXNET) Support 1	ALM eLEXNET support activities to improve performance and functionality with multiple DME initiatives including: eLEXNET home page redesign; GIS Capability; Adding Map-based reports to eLEXNET; New Reporting Interface, access acceleration, design of format; Community tool Upgrades – social media networking; Outreach – PR internal and external; Data Quality Automation; FERN Improvements; Oracle 11g upgrade; Mobile apps with Common Login implementation; Developing Methods Module; Lab expansion; Security; Program Management, O&M.			
287506	FDA ORA ALM Electronic Laboratory Exchange Network	This project includes ALM Electronic Laboratory Exchange			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
	(eLEXNET) Support 2	Network (eLEXNET) activities to improve performance and functionality with in multiple areas. The eLEXNET home page will be redesigned. Geographical Information System (GIS) capability will be enhanced. With the enhanced GIS capability, map-based reports will be added to eLEXNET. Outreach to laboratories that could potentially participate in the Food Emergency Response Network (FERN) will continue, including expanding data exchange with new participating laboratories. As part of the communications with FERN participants, social media and community tool capabilities will be introduced. The technology stack will be upgraded to Oracle 11g. This will put eLEXNET on the same technology stack as Mission Accomplishments and Regulatory Compliance Services (MARCS). This will enable enhanced integration between eLEXNET and MARCS and set up ORA to work better with external partners such as FERN and Department of Homeland Security (DHS). A pilot for supporting mobile applications in FERN participating labs will also be conducted. Mobile applications could potentially in the future support a range of hardware that is not FDA specified as these are external partners. Methods module development will also continue, including the ability to leverage this for ALM Laboratory Information Management System			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		(LIMS).			
287509	FDA ORA ALM Quality Management Information System (QMiS) Support 1	Quality Management information System (QMiS) is a deploying quality management system (QMS) that supports FDA's field investigations enforcement, and scientific laboratory analysis of field samples. QMiS provides robust information technology (IT) support for the accomplishment of ORA's quality management plan in all operational units – in the regional offices, district offices, laboratories, and headquarters. The QMiS encompasses hardware, software, integration assistance, knowledge transfer including training, ongoing support and documentation.			
287514	FDA ORA ALM Quality Management Information System (QMiS) Support 2	This project includes work on Quality Management information System (QMiS) to expand the number of quality processes handled in QMiS, interfacing with other ORA systems, acquisition of additional software licenses to increase stakeholder access, training, and system configuration. Expanded quality processes include Management Review, Control of Non-conformance, and Preventive Action. QMiS will integrate with Regulatory Business Information Services (RBIS) in order to support retaining historical information and providing analysis and reporting capabilities. QMiS will also begin integration with MARCS services in order to integrate seamlessly within ORA			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		work flows. Training will be provided to end users as additional quality processes and other enhancements are rolled out to ORA.			

Activity Summary

Roll-up of Information Provided in Lowest Level Child Activities

Project ID	Name	Total Cost of Project Activities ($M)	End Point Schedule Variance (in days)	End Point Schedule Variance (%)	Cost Variance ($M)	Cost Variance (%)	Total Planned Cost ($M)	Count of Activities
287489	FDA ORA ALM Laboratory Information Management System (LIMS) Proof of Concept							
287491	FDA ORA ALM Laboratory Information Management System (LIMS) Program Management Technical Coordination (PMTC)							
287492	FDA ORA ALM Laboratory Information Management System (LIMS) Laboratory Assessment and Pilots							
287496	FDA ORA ALM Electronic Laboratory Exchange Network (eLEXNET) Support 1							
287506	FDA ORA ALM Electronic Laboratory Exchange Network							

Activity Summary

Roll-up of Information Provided in Lowest Level Child Activities

Project ID	Name	Total Cost of Project Activities ($M)	End Point Schedule Variance (in days)	End Point Schedule Variance (%)	Cost Variance ($M)	Cost Variance (%)	Total Planned Cost ($M)	Count of Activities
	(eLEXNET) Support 2							
287509	FDA ORA ALM Quality Management Information System (QMiS) Support 1							
287514	FDA ORA ALM Quality Management Information System (QMiS) Support 2							

Key Deliverables

Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
287489	287489: LIMS Proof of Concept Analysis	This focused on conducting an analysis of current manual work flows involving the use of the 431 form in ORA laboratories. This form is used by bench analysts to record the actions taken during sample analyses. Data is hand written onto this form. Once complete, the data is manually entered into the legacy MARCS Field Accomplishments and Compliance Tracking System (FACTS). This is an outdated approach to collecting this data and results in a good amount of analyst time being spent on filling out this	2009-12-15	2009-12-15	2009-12-15	75	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		form and entering data rather than conducting lab work. The analysis looked at ways to approach making this form electronic.						
287509	287509: QMiS Release 1.1.1	This is the second release of the MasterControl COTS tool at FDA. This resolves all of the security issues associated with the previous release. This includes work on upgrading the COTS to a newer version, a System Security Plan, and a Contingency Plan.	2010-10-21	2010-10-21	2010-10-21	34	0	0.00%
287509	287509: QMiS Training 1	This includes training for OIM technical personnel and training for end users for Release 1.0. This is focused on getting technical personnel up to speed and getting end users started on limited functionality, mostly related to document control.	2010-11-19	2010-11-19	2010-11-19	63	0	0.00%
287496	287496: eLEXNET Outreach 1	Develop outreach strategies and approaches for reaching out to three pirmary stakeholder groups - state labs, government labs, and private labs. This focuses on reaching	2010-12-31	2010-12-31	2010-12-31	162	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		out to state labs first due to the heavy reliance of these labs on manual data exchange.						
287496	287496: eLEXNET Methods Module 1	Requirements and Design for the Methods Module.	2011-02-28	2011-02-28	2011-02-28	103	0	0.00%
287509	287509: QMiS Training 2	This includes training for OIM technical personnel for Release 1.1. This focuses on producing FDA in house technical expertise.	2011-03-25	2011-03-25	2011-03-25	144	0	0.00%
287496	287496: eLEXNET Common Login 1	Requirements and Preliminary Design for Common Login.	2011-03-31	2011-03-31	2011-03-31	169	0	0.00%
287489	287489: LIMS Proof of Concept Phase 3	Phase 3 focused on analyzing and testing approaches to aggregating data collected from multiple laboratory sites so that it could be automatically picked up and fed back into MARCS FACTS.	2011-04-07	2011-04-07	2011-04-07	164	0	0.00%
287509	287509: QMiS Training 3	This includes training for end users for Release 1.1. This includes the development of training materials and courses for end users.	2011-04-29	2011-04-29	2011-04-29	109	0	0.00%
287496	287496: eLEXNET Outreach 2	Outreach to stakeholder groups with an emphasis on government labs and state lab follow up outreach.	2011-04-30	2011-04-30	2011-04-30	119	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
287496	287496: eLEXNET Outreach 3	Outreach to stakeholder groups with an emphasis on private labs and government and state lab follow up outreach.	2011-07-25	2011-07-25	2011-07-25	85	0	0.00%
287509	287509: QMiS Training 4	This includes training for end users for Release 1.1. This provides full training to end users.	2011-08-26	2011-08-26		73	-371	-508.22%
287492	287492: ALM LIMS LAP Chemistry Lab Pilots Standup Activities	This section consists of the activities involving the kickoff meeting and the integrated baseline review.	2011-12-29	2011-12-29		94	-246	-261.70%
287492	287492: ALM LIMS LAP 2T Lab Assessment Requirements Validation Phase 1	This section consists of the activities that involve Pilot Site information planning, the visits to the Pilot sites, information gathering activities, and preparation for Non Pilot site visits. Also includes evidentiary requirements, verification activities as well performance and capacity requirements.	2011-12-31	2011-12-31		110	-244	-221.82%
287492	287492: ALM LIMS LAP 2T Lab Assessment RTM Phase 1	This section consists of the activities that involve updating the Requirements Traceability Matrix with a focus on the Pilot Sites.	2011-12-31	2011-12-31	2011-12-31	87	0	0.00%
287492	287492: ALM LIMS	This section consists	2011-12-31	2011-12-31		87	-244	-280.46%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
	LAP 2T Lab Assessment SRS Phase 1	of the activities that involve updating the System Requirements Specification with a focus on the Pilot Sites.						
287492	287492: ALM LIMS LAP 2T Lab Assessment BPMPF Phase 1	This section consists of the activities that involve the Business Process Model with a focus on the Pilot sites.	2011-12-31	2011-12-31		79	-244	-308.86%
287492	287492: ALM LIMS LAP Chemistry Lab Pilots Pilot Requirements, System Requirements, and Business Process Modeling	This section consists of the activities involving the Southeast Regional Laboratory (SRL) & Pacific Regional Laboratory (PRL) -Southwest (SW) site visits, as well as updating the RTM, SRS and BPM.	2012-01-11	2012-01-11		107	-233	-217.76%
287491	287491: ALM Laboratory Information Management System (LIMS) Program Management Technical Coordination (PMTC) FY12 H1	This provides program level activities to support work across all of LIMS. LIMS is divided into a set of activities that may be concurrent or sequential and that require a high degree of coordination to ensure the optimum design and ultimate implementation across all 16 FDA ORA labs and integration with other applications associated with MARCS. This will facilitate compliance	2012-03-11	2012-03-11		181	-173	-95.58%

Key Deliverables

Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		with Service Oriented Architecture (SOA) and the Chief Information Officer's (CIO) goals and objectives. ORA has 14 static laboratory locations in buildings and two mobile laboratory units that can be driven to a particular location. PMTC is essential to the management of the LIMS program that will include an comprehensive assessment phase of the current status of the lab systems' environment, IT interface needs, the creation of four Test Labs, determining the design of optimum IT systems, and the implementation in each of the labs. PMTC also includes handling IT security considerations and configuration management across LIMS.						

Section C: Operational Data

Table II.C.1 Performance Metrics

Metric Description	Unit of Measure	FEA Performance Measurement Category Mapping	Measurement Condition	Baseline	Target for PY	Actual for PY	Target for CY	Reporting Frequency
Percentage of user requirements accomplished for portal configuration for eLEXNET. Outcome: Increased user satisfaction and system usage which reduces the use of telephone, etc. This results in greater staff efficiency.	0-100% scale with 100% highest possible score.	Customer Results - Customer Benefit	Over target	15.000000	16.000000	16.000000	20.000000	Semi-Annual
Percentage of identified Standard Operating Procedures under document control and management in QMiS. Outcome: improvement in consistently valid results.	0-100% scale with 100% highest possible score.	Process and Activities - Quality	Over target	0.000000	10.000000	10.000000	100.000000	Semi-Annual
Percentage of ORA labs and District Offices with consistent and well-defined national quality factors in QMiS. Outcome: defined, accepted, universal culture of quality with reduced errors and support for laboratory accreditation. Aligns with 2012 Congressional Justification Performance	0-100% scale with 100% highest possible score.	Process and Activities - Quality	Over target	0.000000	15.000000	15.000000	25.000000	Semi-Annual

Table II.C.1 Performance Metrics								
Metric Description	Unit of Measure	FEA Performance Measurement Category Mapping	Measurement Condition	Baseline	Target for PY	Actual for PY	Target for CY	Reporting Frequency
Measure (CJ) 214206.								
Percentage of labs converted from manual to automated data entry into eLEXNET. Outcome: Reduction in FTE time required and improved response to changing conditions to support protection. Aligns with 2012 CJ 214303 and 214305.	0-100% scale with 100% highest possible score.	Customer Results - Customer Benefit	Over target	15.000000	16.000000	20.000000	25.000000	Semi-Annual
Number of hours of unplanned system downtime for eLEXNET er year. eLEXNET is a 24x7 system. Outcome: Greater reliability and availability in case of a health emergency or bioterrorism threat. Aligns with CJ 214305.	Number of hours of unplanned downtime per year	Technology - Reliability and Availability	Under target	48.000000	24.000000	14.000000	12.000000	Monthly
Number of ORA labs with LIMS functionality. Outcome: increased laboratory surge capacity, improved tracking of inventory - e.g., reagents - and equipment calibration, resulting in cost savings. Provides equipment calibration, records for legal actions. Aligns with CJ 214305.	0-16 reflecting # of fixed/portable labs affected	Technology - Effectiveness	Over target	0.000000	0.000000	0.000000	2.000000	Semi-Annual

Table II.C.1 Performance Metrics

Metric Description	Unit of Measure	FEA Performance Measurement Category Mapping	Measurement Condition	Baseline	Target for PY	Actual for PY	Target for CY	Reporting Frequency